MAR 2 2 2001

K010497

Micro Therapeutics, Inc.
Special 510(k): SilverSpeed® Hydrophilic Guidewire

Attachment 4

510(k) Summary

Prepared February 20, 2001

TRADE NAME	MTI SilverSpeed® Hydrophilic Guidewire		
GENERIC NAME	Guidewire, Catheter		
CLASSIFICATION	Class II (21 CFR 870.1330)		
SUBMITTED BY	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618	**CONTACT**	Eben Gordon Regulatory Affairs (949) 837-3700
PREDICATE DEVICE	MTI SilverSpeed® Hydrophilic Guidewire		
DEVICE DESCRIPTION	The MTI SilverSpeed® Hydrophilic Guidewire is a stainless steel guidewire with a radiopaque, platinum distal coil. The distal section of the guidewire is hydrophilically coated from the shapeable platinum coil up to the proximal section of the guidewire. The proximal portion of the 300 cm guidewire is coated with polytetrafluoroethylene (PTFE). Included within the sterile pouch is a torque device to assist in guidewire manipulation and a guidewire introducer to ease the introduction of the guidewire into the catheter hub and/or hemostasis valve.		
INDICATIONS FOR USE	The MTI SilverSpeed® Hydrophilic Guidewire is intended for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.		
TESTING	Biocompatibility of the MTI SilverSpeed® Hydrophilic Guidewire was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the guidewire when tested as an external communicating, blood contact, limited exposure (<24 hrs) device. In-vitro performance testing of the MTI SilverSpeed® Hydrophilic Guidewire included dimensional inspection, tensile strength tests, torque strength tests, coating performance tests, and performance under simulated conditions. All testing of the product yielded acceptable results.		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI SilverSpeed® Hydrophilic Guidewire is substantially equivalent to the predicate device in intended use and principles of operation.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2001

Mr. Eben Gordon
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K010497
MTI SilverSpeed® Hydrophilic Guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: February 20, 2001
Received: February 21, 2001

Dear Mr. Gordon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

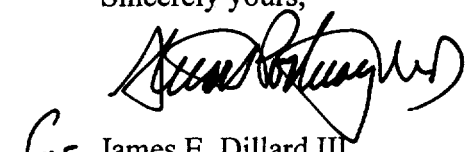
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known): K010497

Device Name: **MTI SilverSpeed® Hydrophilic Guidewire**

Indications for Use: **The MTI SilverSpeed® Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR Over the Counter Use**_____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010497

3-21-01